Exhibit 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** ***The County of Summit, Ohio et al. v. Purdue Pharma L.P., et al.*** **Case No. 17-OP-45004** ***The County of Cuyahoga v. Purdue Pharma L.P., et al.*** **Case No. 18-OP-45090**	**MDL No. 2804** **Case No. 17-md-2804** **Judge Dan Aaron Polster**

NOTICE OF VIDEOTAPED 30(b)(6) (DEPOSITION OF THOMAS PREVOZNIK

PLEASE TAKE NOTICE that, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure and the Deposition Protocol governing this litigation, Track One Defendants,[1] by and through undersigned counsel, will take the oral videotaped deposition of **Thomas Prevoznik**, on

[1] Distributor Defendants named in one or more of the three cases styled above are: Cardinal Health, Inc., McKesson Corporation, AmerisourceBergen Drug Corporation, Rite Aid of Maryland, Inc., CVS Indiana, LLC, CVS RX Services, Inc., Walgreens Boots Alliance, Inc., Walmart Inc. F/K/A Wal-Mart Stores, Inc., H. D. Smith LLC, f/k/a H. D. Smith Wholesale Drug Co., Prescription Supply, Inc., Anda, Inc. and Miami-Luken, Inc. Manufacturer Defendants named in one or more of the three cases styled above are: Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. f/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.); Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; SpecGx LLC; Mallinckrodt LLC; and Insys Therapeutics, Inc.

behalf of the Drug Enforcement Administration ("DEA"), on April 17 and 18, 2019, beginning at 9:00 a.m. Eastern Standard Time at Williams & Connolly LLP, 725 Twelfth St. NW, Washington, DC 20005. The deposition will be on the Topics for Examination—as set forth in the Notice of Videotaped 30(b)(6) Deposition of the Drug Enforcement Administration (Exhibit A), as granted by the Department of Justice on March 25, 2018 (Exhibit B)—for which it has designated Thomas Prevoznik to testify on Defendants' Topics 2, 3, 9, 11, and 12, and Plaintiffs' Topics 1, 2, 4, and 5.

Defendants reserve the right to reschedule or reopen this deposition to the extent relevant materials, including the documents relied upon by the witness, were not produced in compliance with the court's orders concerning production of documents, including (but not limited to) the Special Master's September 6, 2018 Order on Discovery in Track One Cases. The deposition shall be videotaped and recorded stenographically and will continue from day to day until completed before a person duly authorized to administer oaths who is not counsel of record or interested in the events of this case. The oral examination is to be taken for purposes of discovery, for use at trial, or for such other purposes as are permitted under the Federal Rules of Civil Procedure, the local rules of the United States District Court for the Northern District of Ohio, and all Pretrial Orders and Case Management Orders entered by the Court. Court reporting services and video recording services will be provided by Veritext Legal Solutions.

Dated: April 11, 2019

Respectfully submitted,

/s/ Enu Mainigi

Enu Mainigi
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, NW
Washington, DC 20005

Telephone: (202) 434-5000
Fax: (202) 434-5029
emainigi@wc.com

Counsel for Distributor Defendant Cardinal Health, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on April 3, 2019, I caused the foregoing document to be served via email to Plaintiffs Counsel at mdl2804discovery@motleyrice.com.

Dated: April 11, 2019

/s/ Bradley D. Masters
Bradley D. Masters

EXHIBIT A

LAW OFFICES
WILLIAMS & CONNOLLY LLP
725 TWELFTH STREET, N.W.
WASHINGTON, D. C. 20005-5901
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EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

ENU MAINIGI
(202) 434-5420
emainigi@wc.com

July 10, 2018

By Federal Express and Electronic Mail

Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

Re: Subpoenas in *In re National Prescription Opiate Litig.*, MDL No. 2804 (N.D. Ohio)

To whom it may concern:

I write on behalf of Defendants in the matter of *In re National Prescription Opiate Litigation*, MDL No. 2804, pending in the United States District Court for the Northern District of Ohio. Attached please find copies of (1) a federal subpoena for witness testimony calling for your appearance at a deposition, and (2) a federal subpoena for the production of documents. If the exact date and time of deposition listed in the subpoena is not feasible, we are happy to work with you to find another mutually agreeable date, consistent with the accelerated discovery schedule in this matter.

Because this civil discovery demand implicates DOJ *Touhy* regulations and the involvement of the United States Attorney for the Northern District of Ohio, *see* 28 C.F.R. 16.22(b), we are not attempting formal service of process at this time and are instead hoping to enable compliance through the Assistant United States Attorney. I request that you inform me as soon as possible if you will require formal service of process.

Please contact me directly at (202) 434-5000, or emainigi@wc.com, if you have questions concerning these subpoenas or require additional information.

Sincerely,

/s/ Enu Mainigi
Enu Mainigi

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

In re: National Prescription Opiate Litigation
Plaintiff
v.

Defendant

Civil Action No. 1:17-md-02804-DAP

(If the action is pending in another district, state where:

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Drug Enforcement Administration, 8701 Morrissette Dr., Springfield, VA 22152

☑ *Testimony:* **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

See Schedule A.

Place: Williams & Connolly, LLP 725 Twelfth St. NW, Washington, D.C. 20005	Date and Time: 9:00AM, 08/21/2018

The deposition will be recorded by this method: Stenographic and/or by video and audio recording

☐ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 07/10/2018

SANDY OPACICH, CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/ Enu Mainigi
Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing *(name of party)* All Defendants, who issues or requests this subpoena, are:

Enu Mainigi, 725 Twelfth St. NW, Washington, DC 20005, emainigi@wc.com, 202-434-5000

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of

$ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below. Other terms shall have their plain meaning.

1. "You" and "Your" refers to the Drug Enforcement Administration ("DEA") and all others acting or purporting to act on DEA's behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.

2. "Communication" means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.

3. "Defendants" means all defendants named in *In re National Prescription Opiate Litig.*, MDL No. 2804, as of the date of this notice.

4. "Prescription Opioids" means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in Ohio only through prescriptions filled by dispensers duly licensed and regulated.

5. "Illicit Opioids" means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted

6. "DEA Registrant" means Registrant as defined in 21 CFR 1300.01(b) ("any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act").

7. "Chargeback Data" means information that a manufacturer receives from a distributor in connection with a chargeback, a contractual payment from a manufacturer to a distributor made after a distributor sells the manufacturer's product to the distributor's customer for less than the price the distributor paid the manufacturer for the product.

8. "Prescriber Data" means all information related to a person or entity that writes or has written a prescription as defined in 21 CFR. 1300.01(b) ("Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user…").

9. "Suspicious Order Report" means a report filed by DEA Registrants pursuant to 21 CFR 1301.74(b).

10. "ARCOS Data" means data reported by DEA Registrants pursuant to 21 U.S.C. § 827 through the Automation of Reports and Consolidated Orders System.

11. "Opioid Production Quota" means the quantity of Prescription Opioids "necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks" per 21 C.F.R 1303.11.

12. "Opioid Procurement Quota" means the quantity of Prescription Opioids that DEA allows a person or entity to "procure and use… for the purpose of manufacturing such class into dosage forms or into other substances per 21 CFR 1303.12.

TOPICS FOR EXAMINATION

The topics upon which the person or persons designated by You are asked to be prepared to testify in accordance with Rule 30(b)(6) are:

1. The organizational structure of the Office of Diversion Control and the Detroit Diversion Office, the Cleveland, OH Resident Office, the Youngstown, OH Resident Office, the Cleveland Tactical Diversion Squad, and any other unit or subunit of DEA with responsibilities in the state of Ohio.

2. Your interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.

3. Guidance or other Communications provided by You to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74.

4. Your involvement in lawsuits brought against DEA-registered distributors by customers whose orders of controlled substances had been blocked based on the distributor's determination that the orders were "suspicious" pursuant to 21 C.F.R. § 1301.74, or whose ability to purchase controlled substances had been denied or terminated.

5. Your interpretation, enforcement, and practices regarding any obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.

6. The use or potential use of Prescriber Data in connection with any obligation under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.

7. Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.

8. Inquiries or complaints received by You from any government officials of the Ohio Board of Pharmacy, the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or

Cuyahoga County regarding Suspicious Order Reports, or suspected or actual diversion of Prescription Opioids.

9. Your procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS Data, Suspicious Order Reports, or other Communications from DEA Registrants to identify and stop sources of diversion.

10. Investigations or inquiries by You concerning the Defendants.

11. Your practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including DEA's decision to discontinue such practice.

12. Your decision not to allow DEA-registered distributors access to de-identified ARCOS Data prior to February 2018, and its decision to provide DEA-registered distributors with limited access to certain ARCOS Data in February 2018.

13. Your practices and procedures relating to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids.

14. The basis for Opioid Procurement Quotas and Opioid Production Quotas of Prescription Opioids from 1995 to 2018.

15. Your procedures, process, approach, and criteria used to determine the legitimate medical, scientific, and industrial needs for Prescription Opioids and setting Opioid Production Quotas based upon those determinations.

16. Communications between You and any of the Defendants.

17. Communications between You and the Board of Pharmacy of any State, the Attorney General of any State, or government officials of the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County relating to Prescription Opioids or Illicit Opioids.

18. Your policies, procedures, practices, and experience regarding the sharing of ARCOS data with state and local law enforcement entities when requested by them in connection with investigations of or suspicions regarding possible diversion by DEA-registrants in their jurisdictions.

19. Your policies and procedures relating to the "High Intensity Drug Trafficking Areas" (HIDTA) program.

20. The HIDTA program's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County.

21. Your Communications relating to and efforts to comply with the reports and recommendations contained in the following GAO Reports:

    a. *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed: Coordination between DEA and FDA Should Be Improved*, GAO-15-202 (Washington, D.C.: February 2, 2015);

    b. *Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (Washington, D.C.: June 25, 2015);

    c. *Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations*, GAO-16-737T (Washington, D.C.: June 22, 2016).

22. Your expenditure of funds allocated to the Diversion Control Fee Account.

23. Your process for licensing prescribers of controlled substances.

24. Investigation into the retention or removal of documents by Joseph Rannazzisi, and any other former DEA employees currently retained by Plaintiffs.

EXHIBIT B

U.S. Department of Justice

United States Attorney
Northern District of Ohio

United States Court House
801 West Superior Avenue, Suite 400
Cleveland, Ohio 44113-1852
Main: 216-622-3600
Facsimile: 216-522-4982

March 22, 2019

Enu Mainigi
Williams and Connolly LLP
725 Twelfth Street, NW
Washington, DC 20005-5901

Linda Singer
Motley Rice LLC
401 Ninth Street, NW, Suite 1001
Washington, DC 20004

Re: *Touhy* Requests in *In re: National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio)

Dear Counsel:

By letter dated July 10, 2018, the defendants in the above-captioned matter (the Defendants) requested 30(b)(6) testimony from the United States Drug Enforcement Administration (DEA), under the Department of Justice (DOJ's) *Touhy* regulations, 28 C.F.R. § 16.21, *et seq*. The Defendants' 30(b)(6) testimony *Touhy* request was later modified on October 17, 2018, when the Defendants agreed to limit the topics on which 30(b)(6) testimony was requested, and provided further detail on the information encompassed within each topic. Additionally, on December 11, 2018, the plaintiffs in the above-captioned matter (the Plaintiffs) requested 30(b)(6) testimony from the DEA under the DOJ's *Touhy* regulations. By letter dated December 21, 2018, the DOJ summarized its response to the Defendants' narrowed 30(b)(6) *Touhy* request and the Plaintiffs' 30(b)(6) *Touhy* request. We provide this revised letter, which (1) provides the current title for Donetta Spears; (2) corrects a typographical error in Plaintiff's Topic No. 4 to make clear that Thomas Prevoznik will respond to this topic; (3) responds to Defendants' Topic No. 9, which was erroneously excluded from the prior authorization; (4) identifies Mr. Prevoznik as the designated agency witness with respect to Plaintiff's Topic No. 5; and identifies Ms. June Howard as the designated agency witness with respect to Defendant's Topic No. 11.

As you are aware, federal regulations govern the disclosure of official DEA information by federal employees. *See U.S. ex rel. Touhy v. Ragen*, 340 U.S. 462, 468 (1951); *United States v. Wallace*, 32 F.3d 921, 929 (5th Cir. 1994). Under these regulations, current and former DEA

employees are prohibited from disclosing official information in proceedings in which the United States is not a party without express authorization from the DOJ. *See* 28 C.F.R. 16.22(a). "[N]either FOIA nor a third-party subpoena will provide the private litigant with guaranteed access, at public expense, to the testimonial evidence of agency employees. When the government is not a party, the decision to permit employee testimony is committed to the agency's discretion." *COMSAT Corp. v. Nat'l Sci. Found.*, 190 F.3d 269, 278 (4th Cir. 1999).

After careful consultation with the DEA, I have determined that your request for the disclosure of official government information should be granted in part and denied in part. Specifically, I am authorizing the 30(b)(6) testimony below and have identified the DEA witnesses who will provide that testimony.

The two parties have requested deposition testimony as follows:

Topics from Defendants:

Topic 2: Your interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.

- DEA's policies, practices, and guidance relating to whether registrants are permitted to ship orders of controlled substances that the registrant determines to be "suspicious" and/or "excessive," including the nature of the purported duty to conduct due diligence on such orders, as described in the 2006 and 2007 letters from DEA to registrants, and any changes to those policies, practices, and guidance over time;
- DEA's interpretation of, and policies and practices relating to, what constitutes a "suspicious order" under 21 C.F.R. § 1301.74(b), and any changes thereto over time;
- DEA's interpretation of, and policies and practices relating to, registrants' obligations to "know their customers" and/or "know their customers' customers," and any changes thereto over time;
- DEA's communications with third parties concerning potential amendments or updates to 21 C.F.R. § 1301.74; and
- DEA's guidance and/or directions given to registrants about suspicious order reports, including the scope, format, types of systems to be utilized (including automated systems), and DEA locations (field offices or headquarters) for such submissions, and how such guidance and directions changed over time.

****

Mr. Thomas Prevoznik, Associate Section Chief, Pharmaceutical Investigations Section, Diversion Control Division, is authorized to provide testimony on this topic, subject to the following limitations:

First, the fourth sub-topic requests testimony on "DEA's communications with third parties…." By letter dated December 10, the Department of Justice requested that Defendants identify with specificity any "third parties," so that we could determine whether such testimony

may be provided. As we have received no further clarity on the meaning of "third parties," Mr. Prevoznik is not authorized to provide testimony on the fourth sub-topic.

Second, the fifth sub-topic requests testimony on "DEA's guidance and/or directions given to registrants...." As stated in our letter dated December 10, while Mr. Prevoznik will be prepared to speak to industry-wide guidance or directions, he will not be prepared to provide testimony on communications with individual registrants over a more than 20-year time period.

Third, the fifth sub-topic requests testimony on guidance and directions from "DEA locations (field offices or headquarters)." Mr. Prevoznik will be prepared to testify regarding guidance and directions from headquarters as well as DEA's Ohio field office, which accords with the geographic limits set forth by Special Master Cohen in Discovery Ruling No. 3 (Dkt. 762). To the extent necessary and in accordance with discovery orders issued by the Court, the agency is willing to consider providing testimony on this particular sub-topic relating to other field offices at a later date.

Topic 3: Guidance or other Communications provided by You to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74.

- DEA's guidance to registrants relating to whether registrants are permitted to ship orders of controlled substances that the registrant determines to be "suspicious" and/or "excessive," including the nature of the purported duty to conduct due diligence, as described in the 2006 and 2007 letters from DEA to registrants, and any changes in that guidance over time;

- DEA's guidance to registrants relating to what constitutes a "suspicious order" under 21 C.F.R. § 1301.74(b), and any changes in that guidance over time;

- DEA's "Distributor Briefing" initiative, including when these briefings were given and the guidance provided to registrants relating to their obligations under the CSA;

- DEA's guidance to registrants relating to the adequacy of their suspicious order monitoring systems; and

- DEA's guidance to registrants relating to any obligation to monitor registrants' customers and the downstream supply chain.

****

Mr. Prevoznik is authorized to provide testimony on this topic subject to the following limitations:

The topics and sub-topics request "guidance to registrants" on a number of subjects. As stated in our letter dated December 10, while Mr. Prevoznik will be prepared to speak to industry-wide guidance or directions, he will not be prepared to provide testimony on communications with individual registrants over a more than 20-year time period.

Topic 7: Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.

- DEA's macro-level understanding of or assessments relating to the illegal entry, distribution, or use of Prescription Opioids in the State of Ohio, including any trends that have emerged since 2006; and
- DEA's macro-level understanding of or assessments relating to the entry, distribution, or use of Illicit Opioids in the State of Ohio, including any trends that have emerged since 2006.

This topic does ***not*** encompass DEA's understanding of or investigations into individual misconduct or information that would compromise or interfere with national security.

****

Based on the objection to providing testimony on this topic in our December 10 letter, Defendants offered to amend the topic to read: "Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio **where these efforts resulted from reporting of a SOR**."

The amendment does not adequately address the concern that this testimony would require DEA to reveal privileged and law enforcement sensitive information. Accordingly, no testimony is authorized on this topic.

However, by letter dated December 21, 2018, the Department of Justice is authorizing Mr. Keith Martin to provide testimony on his "personal knowledge of DEA's general efforts to combat diversion, respond to the opioid epidemic, and/or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County." As set forth more fully in that letter, Mr. Martin is not authorized to reveal information that is privileged and/or law enforcement sensitive.

Topic 8: Inquiries or complaints received by You from any government officials of the Ohio Board of Pharmacy, the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County regarding Suspicious Order Reports, or suspected or actual diversion of Prescription Opioids.

- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to any registrant's filing of or failure to file Suspicious Order Reports;
- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to the amount of opioid medications distributed by any registrant in the State of Ohio or in the above-listed areas;
- Inquiries by government officials, not including law enforcement agents, from the above-listed entities relating to the causes of the opioid epidemic;

- The total number of inquiries by government officials from the above-listed entities relating to the actual or suspected diversion of Prescription Opioids by DEA Registrants; and

- The nature, timing, and number of corrective actions taken by DEA as a result of inquiries by government officials from the above-listed entities relating to the actual or suspected diversion of Prescription Opioids by DEA Registrants.

This topic does ***not*** encompass DEA's understanding of or investigations into individual misconduct or information that would compromise or interfere with national security.

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As stated in our December 10 letter, inquiries, complaints, or communications to DEA from any Ohio county, city, township, or village that is a party to the MDL should be sought from that party and not from DEA, which is not a party to this litigation. Additionally, the testimony sought would require DEA to reveal privileged and law enforcement sensitive information. While we appreciate that the request purports not to seek "information that would compromise or interfere with national security," such a limitation is insufficient to protect privileged and law enforcement sensitive information. Furthermore, inquiries or complaints of the nature described above are not maintained in a centralized database. Consequently, this request effectively asks DEA to provide testimony on individual communications that may have occurred with an unknown number of individuals, and it would be impractical and unduly burdensome to adequately prepare a witness to provide testimony on this topic. Accordingly, no testimony is authorized on this topic.

However, by letter dated December 21, 2018, the Department of Justice is authorizing Mr. Keith Martin to provide testimony on his "personal recollection of [his] communications with any representative of Summit County, OH; Akron, OH; Cleveland, OH; and/or Cuyahoga County, OH regarding or relating to prescription opioids." As set forth more fully in that letter, Mr. Martin is not authorized to reveal information that is privileged and/or law enforcement sensitive.

Topic 9: Your procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS Data, Suspicious Order Reports, or other Communications from DEA Registrants to identify and stop sources of diversion. This topic encompasses the following subjects:

- DEA's general procedures relating to the analysis of ARCOS data, Suspicious Order Reports, or other Communications from DEA Registrants identifying suspicious orders or customers from 1995 to 2014, but not including DEA's analysis of particular ARCOS data or Suspicious Order Reports.

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Mr. Prevoznik is authorized to provide testimony on this topic, subject to the following limitations:

He will not be permitted to disclose information that is privileged or law enforcement sensitive.

Topic 11: Your practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including when and why you discontinued such practice.

Ms. June Howard, Chief, Targeting & Analysis Unit of the Pharmaceutical Investigation Section of the Office of Diversion Control, is authorized to provide testimony on this topic, subject to the following limitations:

She will not be permitted to disclose communications with counsel. Additionally, if the Defendants have specific documents on which they intend to ask questions, we request that the Defendants provide those documents at least 14 business days in advance of the scheduled deposition date so that the witness may be prepared to answer questions on those documents.

Topic 12: Your decision not to allow DEA-registered distributors access to de-identified ARCOS Data prior to February 2018, and your decisions to provide DEA-registered distributors with limited access to certain ARCOS Data in February.

Mr. Prevoznik is authorized testimony on this topic, subject to the following limitations:

For the reasons stated in our December 10, letter Mr. Prevoznik is not authorized to testify on decisions made in or after February 2018. Additionally, Mr. Prevoznik will not be permitted to disclose communications with counsel or communications that may implicate deliberative process.

Topic 13: Your practices and procedures related to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids.

- DEA's procedures and practices relating to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids, including the factors, resources, or other information that DEA evaluates; and
- DEA personnel involved in the approval of Opioid Procurement Quotas and Opioid Production Quotas.

Topic 14: The basis for Opioid Procurement Quotas and Opioid Production Quotas of Prescriptions from 1995 to 2018.

- DEA's high-level rationale for generally and significantly increasing the Opioid Procurement Quotas and Opioid Production Quotas of Prescription Opioids from 1995 to 2018.

This topic does ***not*** encompass individual quota decisions for particular drugs in particular years.

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Ms. Stacy Harper-Avilla Chief, UN Reporting and Quota Section, Diversion Control Division, is authorized to provide testimony on these topics, subject to the following limitations:

Topics 13 and 14 seek testimony regarding "Opioid Procurement Quotas" and "Opioid Production Quotas," but DEA does not establish any quotas identified as such. Rather, DEA establishes three types of quotas for each basic class of controlled substance listed in Schedule I or II, including several basic classes of opioids. Specifically, DEA establishes an Aggregate Production Quota (APQ), which determines the total quantity of each basic class of controlled substance to be manufactured during the following calendar year. For individual manufacturers, DEA establishes individual Manufacturing Quotas (MQ) authorizing a particular registrant to manufacture a quantity of a specific basic class of controlled substance during the next calendar year. DEA also establishes Procurement Quotas (PQ) authorizing particular registrants to procure and use quantities of each basic class of such substances for the purpose of manufacturing such class into dosage forms or into other substances.

In connection with Topic 13, therefore, DEA will provide testimony describing its practices and procedures relating to the establishment of the APQ, MQs, and PQs prior to 2018 insofar as they relate to basic classes of opioids. In connection with Topic 14, you have indicated in your letter of October 17, 2018 that "this topic does ***not*** encompass individual quota decisions for particular drugs in particular years." (emphasis in original). Thus, our understanding is that Topic 14 does not seek testimony regarding MQs and PQs, each of which encompasses only individual quota decisions. DEA will provide testimony responsive to Topic 14, as clarified in your October 17, 2018 letter, with respect to DEA's establishment of the APQ only. Please note, however, that DEA's decision to authorize testimony in response to these topics does ***not*** imply that DEA accepts the Defendants' characterization of the facts in its 30(b)(6) notice or subsequent communications about these topics.

Topic 20: The DEA's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village or city within Summit County or Cuyahoga County.

- DEA's participation in Opiate Action Team, Summit County Drug Unit, Northern Ohio Law Enforcement Task Force, Cuyahoga County Opiate Task Force, Summit County Opiate Task Force, United States Attorney's Heroin and Opioid Task Force, Ohio High Intensity Drug Trafficking Area, Summit County Drug Unit, and any other task force, organization, and/or committee with responsibilities relating to Prescription Opioids or Illicit Opioids in the state of Ohio; and

- Any assistance, included but not limited to financial grants and training, provided by DEA to the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County to investigate, respond to, or combat drug-related crimes, Prescription Opioid diversion, and/or the unlawful trafficking of Illicit Opioids.

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DEA efforts to combat diversion in these specific localities, as well as throughout the United States, are at the forefront of the agency's mission and are at the center of the day-to-day activities of the DEA's Ohio Field Office. Additionally, DEA's participation in these task forces is a matter of public record. Accordingly, no testimony is authorized on this topic. The DEA

will, however, agree to provide a written response that identifies, for the task forces, units, and working groups specifically identified in the first sub-topic, whether the DEA was involved, if the DEA had a lead or supporting role, and the purpose or mission of the task force, unit, and working group.

Additionally, by letter dated December 21, 2018, the Department of Justice is authorizing Mr. Keith Martin to provide testimony on his "personal knowledge of DEA's general efforts to combat diversion, respond to the Opioid epidemic, and/or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; and/or Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County." As set forth more fully in that letter, Mr. Martin is not authorized to reveal information that is privileged and/or law enforcement sensitive.

Topic 21: Your Communications relating to and efforts to comply with the reports and recommendations contained in the following GAO reports:

a. ***Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed: Coordination between DEA and FDA Should Be Improved*, GAO-15-202 (Washington, D.C.: February 2, 2015);**

b. ***Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (Washington, D.C.: June 25, 2015);**

c. ***Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations*, GAO-16-737T (Washington, D.C.: June 22, 2016).**

- The basis for DEA's representations in its response to Linda Kohn of GAO in Appendix IV of the June 25, 2015 report; and
- Actions DEA has taken to follow the recommendations of GAO in the three reports identified above.

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Ms. Donetta Spears, Executive Assistant to the Deputy Assistant Administrator, Diversion Control Division is authorized to provide testimony on this topic subject to the following limitations:

By letter dated December 10, the Department of Justice requested that Defendants identify with specificity the "actions DEA has taken to follow the recommendations of GAO in the three reports identified above." As we have received no further information from the Defendants, Ms. Spears is not authorized to provide testimony on the second sub-topic.

Topic 23: Your process for registering prescribers of controlled substances.

- The factors DEA considers in registering prescribers of controlled substances under the CSA.

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By letter dated December 10, the Department of Justice requested that Defendants provide additional clarification on what information the Defendants are seeking in light of the unambiguous statutory framework of the Controlled Substances Act and implementing regulations. As we have received no further information from the Defendants, no testimony is authorized on this topic.

Topics from Plaintiffs:

Topic 1: DEA's interpretation of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act") and its implementing regulations, including but not limited to, 21 C.F.R. Part 1300 *et seq.* (including, but not limited to, 21 C.F.R. §§ 1301.11, 1301.74), 21 C.F.R. Part 1305, and 28 C.F.R. § 0.100 with respect to a registrant's obligation to maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances," 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74, including the registrants' duty not to ship suspicious orders, and to "maintain effective controls against diversion" as described in the September 27, 2006, February 7, 2007, and December 27, 2007 letters to registrants.

Mr. Prevoznik is authorized to provide testimony on this topic.

Topic 2: DEA's enforcement activities with respect to registrants who manufacture, prescribe, distribute, or dispense Opioids, including the use, disclosure, and limitations of ARCOS data.

Via telephone conference on December 17, we requested clarification on the information sought by the Plaintiffs on this topic. With respect to the type of enforcement activities that are on interest, counsel for Plaintiffs explained that Plaintiffs seek information regarding administrative actions and/or settlements that the DEA has entered into with any of the Defendants. Plaintiffs further stated that they are not seeking information on specific investigations or investigative techniques. Additionally, with respect to the information sought on the "limitations of ARCOS data," we understand that Plaintiffs are seeking information regarding how and to what extent ARCOS data may be used to further enforcement activities.

Mr. Prevoznik is authorized to provide testimony on this topic, as clarified above.

Topic 3: DEA's establishment of quotas for the production of Opioids in the United States, including aggregate production quotas, individual quotas and procurement quotas; disclosure of quota to registrants; communications with registrants regarding quota requests and the disposition of quota requests; and the relationship between quota, suspicious orders, diversion, and lawful medical, scientific, or industrial channels or use.

Ms. Harper-Avilla is authorized to provide testimony on this topic, subject to the same limitations set forth with respect to the Defendants' Topics 13 and 14 above.

Topic 4: DEA's guidance to registrants and requests for guidance from registrants with respect to any of the topics in this subpoena, including, but not limited to, all guidance and communications related to DEA's Distributor Initiative.

Mr. Prevoznik is authorized to provide testimony on this topic, subject to the following limitations:

As stated above with respect to Defendants' Topics 2 and 3 above, while Mr. Prevoznik will be prepared to speak to industry-wide guidance or directions, he will not be prepared to provide testimony on communications with individual registrants over a more than 20-year time period. Additionally, at this time, the DEA is producing Distributor Initiative documents only insofar as they relate to the Track One Defendants.

Topic 5: DEA's interaction with the Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")) regarding best practices, guidance, or enforcement related to registrants' obligations under the CSA and its implementing regulations, as laid out in Topic 1.

Mr. Prevoznik is authorized to provide testimony on this topic, subject to the following limitation:

While Mr. Prevoznik will be prepared to speak generally to the interactions with HDMA or HDA, he will not be prepared to provide testimony on all communications with HDMA or HDA over a more than 20-year time period.

***

The above-named witnesses are not authorized to give testimony on any matter other than that which concerns the above-stated topics and information. Topics on which these witnesses are not authorized to testify include:

A. Information regarding any specific non-public DEA investigations or activities;

B. Classified and classifiable information;

C. Information that would reveal the internal deliberative process within the United States Department of Justice, including the DEA, the United States Attorney's Office, and/or any other federal departments or agencies;

D. Information that would reveal a confidential source or informant;

E. Information the disclosure of which would violate a statute, including laws governing grand jury proceedings;

F. Information that could threaten the lives or safety of any individual, including home addresses of law enforcement personnel;

G. Information that could interfere with ongoing investigations and/or prosecutions;

H. Information that could reveal investigative or intelligence gathering and dissemination techniques whose effectiveness would be thereby impaired;

I. Privileged attorney-client information;

J. Information that would reveal attorney work product or matters of prosecutorial discretion;

K. Expert opinion testimony related to non-public facts or information acquired as part of your performance of your official duties;

L. Personal opinions regarding non-public facts or information acquired as part of your performance of your official duties; and

M. Any non-public recommendations you made or you were aware of concerning any proposed agency action.

In light of the significant volume of information, including documents, testimony, and interrogatory responses, available to the parties but that has not been provided to the Department of Justice or the DEA as a non-party, the United States requests the parties to provide copies of any information that any party believes may assist the designated DEA witnesses with providing responsive, helpful testimony in the MDL and further streamlining the issues. We request that any such materials be provided as soon as possible, but no less than 14 business days before the date of the witness' deposition. Please note, however, that the witnesses offering 30(b)(6) testimony on behalf of the DEA will review and consider any such information only insofar as it is germane to the topics on which they are testifying and to the extent that the volume of information may reasonably be reviewed advance of the deposition.

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Please contact Assistant U.S. Attorney James Bennett (216-622-3988) or Senior Counsel Natalie Waites (202) 616-2964 to discuss mutually agreeable times for the deposition testimony I have authorized.

Sincerely,

AVA ROTELL DUSTIN
Executive Assistant United State Attorney
Office of the U.S. Attorney for the Northern District of Ohio
Acting Under Authority Conferred by 28 U.S.C § 515